

### REMARKS

In the office action mailed July 18, 2003, the Examiner rejected claim 52 under 35 U.S.C. §112, first paragraph. Claims 25-27, 31-33, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen. Applicants respectfully request reconsideration of the application in view of the following comments.

#### Rejection Under 35 U.S.C. §112

In the office action, the Examiner rejected claim 52 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claim 52 recites that the flow control device additionally comprises a frame coupled to the valve body. The Examiner asserted in paragraph 2 of the office action, that "the specification does not support the frame being coupled ("defined as "linked" or "connected") to the valve body."

Applicants respectfully disagree. Merriam-Webster's Collegiate Dictionary provides several definitions for the word "coupled", including "to connect for consideration together", "to join for combined effect", and "to fasten together." (See excerpt from Merriam-Webster's Collegiate Dictionary, Tenth Edition, attached hereto as Exhibit A.) The specification provides support for the frame being "coupled" to the valve body under any of the foregoing definitions. Figures 1 and 2 of the specification, for example, show one possible embodiment of a flow control device where the valve body 24 is coupled to the frame 30 via a valve support 22. The valve support 22 provides a connection or a link between the valve body 24 and the frame 30. Although the valve body 24 and frame 30 are not directly contacting one another in Figures 1 and 2, Applicants note that

the foregoing definitions do not require direct contact between two elements.

Thus, the frame 30 is shown "coupled" to the valve body 24 in Figures 1 and 2.

Figure 8 shows another embodiment of the flow control device wherein the frame is coupled to the valve body and directly contacts the valve body. As described in the last paragraph of page 7 (which extends through page 8) of the specification, Figure 8 shows a conically shaped portion 50 of the frame 46, which provides a passageway 52 for operation of the valve mechanism. As stated on page 8, lines 7-8, the "valve body 56 [of the frame 46] extends across the passageway 52." Thus, Figure 8 and the corresponding description describe another embodiment of a flow control device where the frame is coupled to the valve body, thereby providing further support for claim 52.

In support of the rejection of claim 52 under Section 112, the Examiner stated that "on page 6, lines 9-16 [of the specification], applicant teaches opposite of this claim limitation, specifically that a cylindrical element 36 between disk elements 38, 40 is used to separate the valve body from the seal, within which the frame is located." The examiner seems to imply that the use of the word "coupled" to describe two items precludes the two items from being separated by an intermediate item. However, the definitions of the word "coupled" do not provide such a preclusion and the examiner has provided no support for such an interpretation of the word "coupled." Thus, the description at page 6, lines 9-16, which describes an intermediate structure between the frame and valve body, is in no way at odds with the frame being "coupled" to the valve body.

The examiner further stated that "[t]he specification teaches separating the valve body and the frame so that the valve body will not be distorted when the

frame expands." As discussed, use of the word "coupled" to describe two items does not preclude the two items from being physically separated, as it is still possible for the two items to be indirectly connected by an intermediate item. Nor does the use of the word "coupled" to relate the frame to the valve body indicate one way or the other whether the frame expansion distorts the valve body. Thus, although claim 52 recites that the frame is coupled to the valve body, the claim is silent as to whether or not the frame expansion distorts the valve body. Consequently, the use of the word "coupled" to relate the frame to the valve body is in no way opposite the description in the specification.

In view of the foregoing, applicants respectfully submit that the rejection of claim 52 under Section 112 should be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 25-27, 31-33, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen. However, Applicant respectfully submits that the claims recite subject matter that is neither taught nor suggested by either Leonhardt or Andersen, both alone and in combination. For example, independent claim 25 recites the steps of placing in a pulmonic passageway a flow control device which has a resilient seal secured to a valve body. Both Leonhardt and Andersen fail to teach or suggest a flow control device which has a resilient seal. Accordingly, Applicants respectfully submit that the rejection of claims 25-27, 31-33, and 52 should be withdrawn.

Leonhardt describes a valve stent 20 comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. In paragraph 4 of the office action, the examiner asserted that the graft material 24 corresponds

to the "resilient seal" of claim 25. However, unlike the resilient seal recited in claim 25, the graft material 24 is not resilient. Leonhardt describes the graft material 24 at column 5, lines 53-61, stating that the graft material 24 "is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as polyester or PTFE." Nowhere in this description nor in any other part of the specification does Leonhardt state or even imply that the graft material 24 can be a resilient material. Indeed, at column 5, lines 59-61, Leonhardt states that the graft material 24 is tapered in order to prevent bunching of the graft material once placed in the patient. It is unlikely that a resilient material would bunch, as a resilient material would have the ability to recover its shape after deformation. This indicates that the graft material of Leonhardt is not resilient.

Rather than showing a graft material that is resilient, Leonhardt indicates that the graft material 24 is a material that passively conforms to the shape of the stent 26 to which it is attached. For example, Leonhardt describes at column 5, line 62 through column 6, line 8 how the graft material is attached to the stent 26 so that the material conforms tightly to the stent. Any resilient characteristics of the Leonhardt valve stent are provided solely by the stent 26, which is formed of a nitinol wire having superelastic characteristics. Leonhardt provides no suggestion or motivation for modifying the graft material to be resilient.

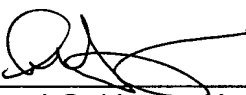
Andersen also fails to teach or suggest a flow control device which has a resilient seal that seals with a wall of a pulmonic passageway. Andersen describes a valve prosthesis for implantation in the body. The valve prosthesis includes a tubular means 24 having a cylinder surface that secures the valve prosthesis in a body channel by abutting the body channel. Anderson never shows that the tubular means is a resilient material. Rather, Andersen simply

states that the cylinder surface is closed by a "suitable material." See Andersen, col. 4, lines 3-5. Moreover, Andersen has no suggestion or motivation to make the cylinder surface a resilient material. In view of the foregoing, the rejection of claim 25 under 35 U.S.C. §103(a) should be withdrawn.

Claims 26-27, 31-33, and 52 depend from claim 25 and all of these claims recite subject matter that is neither taught nor suggested by the cited art. In addition, these claims are patentable in view of their dependence on claim 25.

If the Examiner has any questions regarding the foregoing, she is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,  
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## **EXHIBIT A**



# Merriam- Webster's Collegiate® Dictionary

TENTH EDITION

Merriam-Webster, Incorporated  
Springfield, Massachusetts, U.S.A.



# A GENUINE MERRIAM-WEBSTER

The name *Webster* alone is no guarantee of excellence. It is used by a number of publishers and may serve mainly to mislead an unwary buyer.

*Merriam-Webster*™ is the name you should look for when you consider the purchase of dictionaries or other fine reference books. It carries the reputation of a company that has been publishing since 1831 and is your assurance of quality and authority.

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**country** *\kən-trē\ n, pl countries* [ME *contree*, fr. OF *contrée*, fr. ML *contrata*, fr. L *contra* against, on the opposite side] (13c) 1: an indefinite usu. extended expanse of land: REGION 2 a: the land of a person's birth, residence, or citizenship b: a political state or nation or its territory 3 a: the people of a state or district: POPULACE b: JURY c: ELECTORATE 2, 4: rural as distinguished from urban areas 5: COUNTRY MUSIC — **country-ish** *\-trē-ish\ adj*

**country** *adj* (14c) 1: of, relating to, or characteristic of the country 2 a: of or relating to a decorative style associated with life in the country (an English ~ look); also: possessing a style of rustic simplicity (~ furniture) b: prepared or possessed with farm supplies and procedures (~ ham) 3: of, relating to, suitable for, or featuring country music (~ singers)

**country and western** *n* (1960): COUNTRY MUSIC — usu. hyphenated in attributive use

**country club** *n* (1867): a suburban club for social life and recreation; esp.: one having a golf course — usu. hyphenated in attributive use

**country-dance** *\kən-trē-dan(t)s\ n* (1579): any of various native English dances in which partners face each other esp. in rows

**country gentleman** *n* (1632) 1: a well-to-do country resident: an owner of a country estate 2: one of the English landed gentry

**country house** *n* (14c): a house and esp. a mansion in the country

**country-man** *\kən-trē-mən\ n* (14c) 1: an inhabitant or native of a specified country 2: COMPATRIOT 3: one living in the country or marked by country ways: RUSTIC

**country mile** *n* (1950): a long distance

**country music** *n* (1952): music derived from or imitating the folk style of the Southern U.S. or of the Western cowboy

**country rock** *n* (1968): ROCKABILLY

**country-seat** *\kən-trē-sēt\ n* (1583): a house or estate in the country

**country-side** *\kən-trē-sīd\ n* (1727) 1: a rural area 2: the inhabitants of a countryside

**country-wide** *\kən-trē-wīd\ adj* (1915): extending throughout a country

**country-woman** *\kən-trē-wū-mən\ n* (15c) 1: a woman compatriot 2: a woman resident of the country

**county** *\kaun-tē\ n, pl counties* [ME *countie*, fr. MF *comité*, fr. ML *comitatus*, fr. LL *officium* of a count, fr. *comit-*, comes count — more at COUNT] (14c) 1: the domain of a count 2 a: one of the territorial divisions of England and Wales and formerly also of Scotland and Northern Ireland constituting the chief units for administrative, judicial, and political purposes b: (1): the people of a county (2) Brit: the gentry of a county 3: the largest territorial division for local government within a state of the U.S. 4: the largest local administrative unit in various countries — **county adj**

**county agent** *n* (1705): a consultant employed jointly by federal and state governments to provide information about agriculture and home economics

**county court** *n* (1639): a court in some states that has a designated jurisdiction usu. both civil and criminal within the limits of a county

**county fair** *n* (1856): a fair usu. held annually at a set location in a county esp. to exhibit local agricultural products and livestock

**county palatine** *n* (15c): the territory of a count palatine

**county seat** *n* (1803): a town that is the seat of county administration

**county town** *n* (1670) chiefly Brit: COUNTRY SEAT

**coup** *\kōp\ vb* [ME, to strike, fr. MF *couper* — more at COPE] (1791) 1: to cut, strike, or sever 2: to overthrow, upset

**coup** *\kū\ n, pl coups* *\kūz\* [F, blow, stroke — more at COPE] (1791) 1: a brilliant, sudden, and usu. highly successful stroke or act 2: COUP D'ÉTAT

**coup de grâce** or **coup de grace** *\kū-də-ˈgrās\ n, pl coups de grâce* (1699) 1: a death blow or shot administered to end the suffering of one mortally wounded 2: a decisive finishing blow; act; or event

**coup de main** *\ma\ n, pl coups de main* *\kū-də-ˈmā\* [F, lit., hand stroke] (1758): a sudden attack in force

**coup d'état** or **coup d'état** *\kū-də-ˈtā\ n, pl coups d'état* (1646) 1: a sudden decisive exercise of force in politics; esp.: the violent overthrow or alteration of an existing government by a small group

**coup de théâtre** or **coup de théâtre** *\kū-də-ˈtā-trā\ n, pl coups de théâtre* (1747) 1: a sudden sensational turn in a play; also: a sudden dramatic effect or turn of events 2: a theatrical success

**coup d'oeil** *\kū-də-ˈrē\ n, pl coups d'oeil* *\sāmē\* [F, lit., stroke of the eye] (1739): a brief survey: GLANCE

**coupé** or **coupe** *\kū-pā\ n* (1834) 1: a four-wheeled closed horse-drawn carriage for two persons inside with an outside seat for the driver in front 2: a 2-door automobile often seating only two persons; also: one with a tight-spaced rear seat — compare SEDAN

**couple** *\kōpəl\ n* (13c) 1: a pair, bond, fr. OF *copla*, fr. L *copula* bond, fr. *cop-* + *plere* to fasten — more at APT (13c) 1 a: a man and woman married, engaged, or otherwise paired b: two persons paired together 2: PAIR, BRACE 3: something that joins or links two things together: as a: two equal and opposite forces that act along parallel lines b: a pair of substances that in contact with an electrolyte participate in a transfer of electrons which causes an electric current to flow 4: an indefinite small number: FEW (a ~ of days ago)

**couple** *adj* (1924): TWO; also: FEW — used with a (a ~ drinks)

**usage** The adjective use of a couple, without of, has been called non-standard, but it is not. In both British and American English it is standard before a word (as more or less) indicating degree (a couple more examples of Middle English writing — Charles Barber). Its use before an ordinary plural noun is an Americanism, common in speech and in writing that is not meant to be formal or elevated (the first

couple chapters are pretty good — E. B. White (letter))

**couple** *vb* (1548) *archaic*: the act or result of coupling

**couple-ment** *\kō-pəl-mənt\ n* [MF, fr. *coupler*, to join, fr. *copula*] (1548) *archaic*: the act or result of coupling

**coupler** *\kō-pəl-ər\ n* (1552) 1: one that couples 2: a device for joining a keyboard instrument by which keyboards are connected to play together

**couplet** *\kō-plət\ n* [MF, dim. of *couple*] (1580) 1: two lines of verse forming a unit marked usu. by rhythmic correspondence, or the inclusion of a self-contained utterance 2: a couplet 3: one of the musical episodes alternating with the main (as in a rondo)

**coupling** *\kō-plīg\ (usual for 2), -pəl-īg\ n* (14c) 1: the act of coming together: PAIRING; specif.: sexual union 2: joining of or the part of the body that joins the hindquarters of a quadruped 4: a means of electric connection of electric circuits by having a part common to both

**coupon** *\kū-pān\ n* [F, fr. OF, piece, fr. *couper* to cut, at COPE] (1822) 1: a statement of due interest to be cut from a bond when payable and presented for payment; also: the interest, or accommodation: as a: one of a series of attached certificates often to be detached and presented as needed b: a form or form authorizing purchases of rationed commodities c: a date or similar evidence of a purchase redeemable in part of a printed advertisement to be cut off to use as an order

**coupon-ing** *\kū-pā-nīng\ n* (1954): the distribution or redemption of coupons

**courage** *\kō-rāj\ n* [ME *corage*, fr. OF, fr. *cur*, to venture, more at HEART] (14c) 1: mental or moral strength to venture, and withstand danger, fear, or difficulty

**syn** COURAGE, METTLE, SPIRIT, RESOLUTION, TENACITY mean mental strength to resist opposition, danger, or hardship. COURAGE implies firmness of mind and will in the face of danger, or difficulty (the courage to support unpopular causes). METTLE suggests an ingrained capacity for meeting strain or difficulty with fortitude and resilience (a challenge that will test your mettle). SPIRIT also suggests a quality of temperament enabling one to hold one's own or up one's morale when opposed or threatened (her spirit was unbroken by failure). RESOLUTION stresses firm determination to achieve one's ends (the resolution of pioneer women). TENACITY adds to RESOLUTION implications of stubborn persistence and unwillingness to admit defeat (held to their beliefs with great tenacity).

**courageous** *\kō-rā-jəs\ adj* (14c): having or characterized by courage

**courageously** *adv* (14c): in a courageous manner

**courante** *\kū-rānt\ n* [MF, fr. *courir* to run, fr. L *curre*, to run] (1586) 1: a dance of Italian origin marked by quick running steps

**courre** *\kū-rē\ n* (1586) 1: a dance of Italian origin marked by quick running steps

**courre de bois** *\kū-rē-də-ˈbwa\ n, pl coursers de bois* [CanF, lit., woods runner] (1700): a French or métis trapper of America and esp. of Canada

**courgette** *\kūr-zhēt\ n* [F, dim. of *courge* gourd, fr. L *cucurbita*] (1931) chiefly Brit: ZUCCHINI

**courier** *\kūr-ē-ər\ n* [F, *cour-ē*, *kō-rē* *n* [MF *courrier*, fr. *Old* *corriere* to run, fr. L *curre*, to run] (1579) 1: MESSENGER, as a: a member of a diplomatic service entrusted with bearing messages b: (1) an espionage agent transferring secret information (2) a runner of mail or a member of the armed services whose duties include carrying mail, information, or supplies 2: a traveler's paid attendant; esp.: a tourists' guide employed by a travel agency

**cours** *\kōrs\ n* [ME, fr. OF, fr. L *cursum*, fr. *currere* to run, more at CAR] (14c) 1: the act or action of moving in a path from point to point 2: the path over which something moves or extends as a: RACECOURSE b: (1) the direction of travel of a vehicle (as a ship or airplane) usu. measured as a clockwise angle from north; also: the projected path of travel (2) a point of the compass c: WATER COURSE d: GOLF COURSE 3: a chosen manner of conducting oneself: way of acting (our wisest ~ is to retreat) c: (1): progression through a development or period or a series of acts or events (2): LIFE HISTORY, CAREER 4: an ordered process or succession: as a: a number of lectures or other matter dealing with a subject; also: a series of such courses constituting a curriculum (a premed ~) b: a series of doses or medications administered over a designated period c: a part of a meal served at one time b: LAYER; esp.: a continuum level range of brick or masonry throughout a wall c: the lowest rail on a square-rigged mast — **in due course**: after a normal passage of time: in the expected or allotted time — **of course** 1: following the ordinary way or procedure 2: as might be expected

**course** *vb* *coursed*; **coursing** *vi* (15c) 1: to follow close upon

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